CIGAR RIGHTS OF AMERICA

Dear Director Donovan and Administrator Shelanski:

Thank you again for taking the time to meet with Cigar Rights of America's consulting team in May to discuss the issues relating to premium cigars in FDA's final Deeming regulation. We appreciated you taking the time to hear more about our concerns with the proposed rule and our suggestions for solutions in the final rule.

As we discussed, we believe that FDA's proposed Option 2 (with a slight modification), which would exempt premium cigars from the rulemaking, is most justified by the facts and analysis and is the action the Agency should adopt in the final rule. The regulation of premium cigars would be so costly as to more than decimate the small businesses that make up the premium manufacturing industry, and lead to serious unintended consequences, both for industry and for FDA, and it would be of insignificant benefit to the public.

You asked us to write you and to provide additional information and evidence to support our position, and we welcome the opportunity to do so. Below, please find that evidence. We show that there does not exist a youth access problem with respect to premium cigars, and thus that restrictions on them are not likely to significantly reduce youth smoking. We show that FDA regulation is likely to lead to tens of thousands of lost jobs domestically and internationally, even by FDA's own account. We should note that FDA's rule is most likely to result in the perverse consequence of driving small businesses from the marketplace and consolidating the hold the largest, multi-national tobacco companies. We show that FDA's $10 price criterion for premium cigars is ultimately unworkable and that it is unnecessary to achieving the agency's goals. And finally, we show that FDA's economic analysis does not meet the requirements of Executive Order 12866 and that the agency failed to even estimate one of the rule's primary cost drivers.

We hope that this information will be helpful to you and your staff as OIRA reviews FDA's draft final rule. If you have other questions or if there is additional information that we can provide, please don't hesitate to let us know.

Sincerely,

Glynn Loope
Executive Director, Cigar Rights of America

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Executive Summary

- Youth Do Not Smoke Premium Cigars in Substantial Numbers
  - Reasonable analysis shows that a **maximum** of 0.17% of high school students had smoked even one premium cigar
  - That figure has been in significant decline since 2011
  - Premium cigars are uniquely designed and priced for adults

- Inclusion of Premium Cigars Would Result in Loss of Tens of Thousands of Domestic Jobs
  - Even FDA's own analysis assumes nearly 50% losses in the premium market, and their analysis omits key cost drivers

- Inclusion of Premium Cigars Would Have Serious International Effects
  - Job losses would be in the tens or hundreds of thousands throughout Latin America
  - The rule might constitute a WTO Technical Barrier to Trade
  - Inclusion of premiums would have economic and trade effects that would have national security and diplomatic ramifications

- Rule Would Allow Largest Firms to Monopolize Marketplace

- FDA's Estimated Costs Are Extremely Large and Fail to Account for Key Cost Drivers

ACTION:

- Finalize Option 2, An Exemption for Premium Cigars

- Eliminate Unworkable $10 Price Criterion to Qualify as "Premium," but Tighten Weight Criterion to Prevent Regulatory Arbitrage

Youth Do Not Smoke Premium Cigars

Youth Access to Tobacco

CRA unequivocally opposes youth access to tobacco products of any kind, including premium cigars. We support efforts to ensure that minors are denied access to these products, while maintaining that adults should continue to be free to enjoy premium cigars, should they choose to do so. We believe existing laws prohibiting the sale of tobacco products to minors and providing for inspections of premium cigar retail establishments are working and the premium cigar industry is wholeheartedly committed to enforcement of those laws.

One of the primary goals of the Family Smoking Prevention and Tobacco Control Act, and FDA's efforts in implementing that Act, is to ensure that children are protected from tobacco. FDA has said that there is a youth smoking "epidemic" that is partially the result of access to premium cigars. Children should not be permitted under any circumstances to purchase tobacco products, nor should companies or retailers engage in any marketing designed to attract minors.

CRA supports these goals, but any regulatory solutions must take into account the facts of youth usage and target the actual source of the problem. The fact is that no more than 0.17% of high school students report having smoked even one premium cigar in the last 30 days, and that this number continues to be in decline. While no youth should use tobacco products, this figure cannot possibly constitute an epidemic and is not growing – and FDA's regulation is not the right tool to address it.

Youth Use of Premium Products is Already Insignificant and in Decline

According to the CDC's Spring 2015 National Youth Tobacco Survey (NYTS), high school students who had smoked even one cigar (including both premiums and mass-market products) in the last 30

days fell from 11.6% to 8.2% over the 2011 – 2014 period.[1] As explained below, it is reasonable to extrapolate from this data that there are nearly no reports of youth access to premium products.

Although the NYTS data does not have sufficient granularity to distinguish premium cigars from mass-market cigars, CRA believes that the vast majority of youth usage of cigars falls under the latter category. The overwhelming majority of cigars sold in the United States are mass-market products. For instance, in 2011, 281 million handmade cigars were imported into the US, as compared to nearly 13 billion that were machine made. That implies that, if minors smoked premium products at the same rate that they smoked mass-markets, youth usage in 2014 would be less than 2.16% of that 8.2%. In other words, if the NYTS data broke out premium cigars as a category, we would expect that no more than 0.17% of high school students to have used premium products. But CRA believes that this would actually represent a dramatic overestimate, because teens are not equally likely to select both products. For reasons that we will expand on, we believe that nearly all of the youth use in the cigar category is of mass-market brands. The Center for Tobacco Products has recognized this and stated that it believes that youth are more likely to be attracted to mass-market products because of price, characterizing flavors, ease of inhalation, and other inherent characteristics of those cigars.

Price and Access

One of the most significant barriers to premium cigars for minors is cost. Minors are particularly price sensitive, and mass-market cigars are cheaper than premiums. A single premium cigar might retail for $5, whereas some mass-market products that imitate cigarettes sell for less than $5 for an entire pack of 20. Price-sensitive customers are much more likely to select lower-cost options, which would tend to shift these consumers away from premium products.

Retail establishments where premium cigars are sold are also not conducive to the presence of minors. CRA and its members have worked aggressively to prevent youth from accessing our manufacturers products, and we have drafted a code of conduct that explicitly forbids any kind of marketing or sales that might be attractive to youth.

Premium Products Are Not Designed to Be Attractive to Youth

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1 By comparison, over the same time period, high school students' use of hookah tobacco rose from 4.1% to 9.4%. And use of e-cigarettes dramatically escalated from 1.5% to 13.4% to become the single most-used category for teens.

Premium products are also not designed to appeal to youth. Premium cigars typically do not have a characterizing flavor, other than natural tobacco, and their packaging, sale, and marketing is not directed to minors. While the vast majority of mass-market products are also enjoyed by adults, there is evidence that some of them also appeal to youth. Mass-market products are much more likely to have characterizing flavors, which may be more attractive to youth, and some products have flavorings that may be disproportionately appealing to youth: cotton candy, grape, and similar sweet tastes. In some cases, these products may have packaging and marketing that may also appeal more strongly to children: bright colors and fonts, et cetera. In addition, many mass-market cigar products imitate cigarettes by using similar construction, size, and packaging.

CRA believes that, in crafting its regulatory policy, FDA should take these facts and trends into account and focus its efforts where they are most appropriate. Youth access to all kinds of cigars is already in statistically significant decline, and premium cigar products represent are likely to represent an almost totally insignificant portion of those figures. Therefore, FDA has not demonstrated that youth access to premium cigars is a substantial problem in need of a regulatory solution at this time.

The Rule Would Result in the Loss of Tens of Thousands of Domestic, Cigar-Related Jobs

Nearly all premium cigar manufacturers are small businesses, and the economic effects of the Deeming rule will be crippling for them, and for workers in associated industries such as distribution and independent sales. The effects are devastating even by FDA's own account, which we can demonstrate fails to take into account some of the most substantial costs of the rule.

In the preliminary regulatory impact analysis, FDA estimates that as much as 50% of premium manufacturing may cease as a result of regulation. As we describe below, FDA failed to estimate the costs of required constituent testing – costs which are extremely significant and dramatically increase the total price of compliance for small manufacturers. Therefore, FDA's 50% estimate should probably be viewed as a lower bound for the real losses. In all likelihood, inclusion of the premium sector in the regulatory regime described by the proposed rule would result, in all probability, in 80% of manufacturers being forced to cease production. Nearly all of premium manufacturing takes place overseas (we describe these effects below), but the premium industry still supports tens of thousands of domestic jobs,

many of which would be lost under FDA regulation. We attempt to roughly estimate these job losses and to refine that figure using a Cobb-Douglas production function – both of which support the contention that 20,000 – 30,000 domestic jobs would be threatened by the proposed regulations.

To come up with a rough, first-order estimate, we can calculate the jobs involved in distribution and sales of premium cigars. There are approximately 5,000 brick and mortar retailer cigar stores in the US. These stores typically have two full-time employees and three part-time employees, for a total of 3.5 jobs per location, or 17,500 total jobs. We conservatively assume an additional 5,000 jobs for distribution, administration, and other associated positions: a total of 22,500 jobs, of which 50% to 80% may be lost.

To provide additional support, we have also used information about the premium cigar market in the United States in a Cobb-Douglas production function, which should provide useful data on the total number of jobs supported by the sector (including fractional jobs). To model the market, some assumptions must be made, most notably average premium price at retail. While most CRA members have a high average retail price, we model $4, $5, and $6, finding a range of total jobs in the premium arena from 17,322 to 29,042. (For more information on these calculations, see associated Cobb-Douglas figures.) Again, we believe that a minimum of 50% and more likely 80% of those positions would be lost under FDA regulation.

Sampling and Trade Shows

Inclusion of premium cigars in FDA's final rule would also have substantial negative impacts on local economies by dramatically curtailing trade shows. FDA's proposed rule would ban sampling of deemed products. The primary purpose of these trade shows is to give away free samples and to expose consumers and retailers to new and revised products. Just as wine merchants sample wine to determine which products to stock each year, so too do premium retailers. FDA's proposed sampling ban would almost completely obviate the need for such trade shows and would like lead to many or most being scaled back or canceled.

The trade shows generate both substantial business for the premium cigar industry and large revenues for locales where they are held (Florida, Louisiana and Nevada, for example.) A single recent industry show yielded $16 million in direct and indirect spending and $1.4 million in state and local taxes. These shows are a substantial benefit that will be lost if premium cigars are included in the rule.

Further, premium cigar events are held in all fifty states, most of which are built around the marketing promotion of limited free samples for adult consumers. For example, there are two events in the Commonwealth of Pennsylvania that combined, bring 7,000 adults together for cigar festival oriented events, and the same is the case in Florida and Nevada. Smaller regional events are literally held throughout the nation, thus making the rule adversely impact tourism and hospitality sector industries that depend upon the premium cigar industry.

International Effects

Economic Impacts on Foreign Countries

Under Executive Orders 12866 and 13563, FDA is required to take into account, and to include in its economic analysis of the proposed Deeming rule, any trade and international economic impacts that may result from the provisions. FDA has not done this, and the Agency ignores substantial costs for foreign growers and potentially extremely large job losses in foreign countries.

95% of handmade cigars are manufactured in foreign countries, primarily in Latin America. In Honduras, Nicaragua and the Dominican Republic alone, handmade cigars account for over 350,000 estimated jobs in the agricultural, craftsman, production, support services and distribution sectors. Premium cigar tobacco also create jobs in Cameroon and the Central African Republic – about 3,000 jobs in each country as well as Ecuador, Brazil, Columbia, Puerto Rico, Costa Rica, Peru, Panama, Indonesia, and Mexico. Each of these countries is certain to experience the adverse economic consequences of the FDA rule. While it is difficult to assign precise job-loss figures, FDA's own analysis claims that as many as 50% of cigar brands will be eliminated from commerce, a figure that CRA believes (and elsewhere demonstrates) is a lower bound estimate. Those figures imply huge losses of revenue in all affected countries and threaten 50%-80% of the 350,000 jobs throughout the Latin American premium cigar supply chain.

The governments of these countries have on several occasions communicated their concerns to their counterparts in the State Department and National Security Council and the former Ambassador to the United States from the Dominican Republic testified before the House Foreign Affairs Committee's Subcommittee on Western Hemisphere that the proposed regulations would have a dramatic

impact on that nation’s people. Nevertheless, FDA has failed to take into account the concerns as expressed by the Ambassador about the economic and political consequences for his country.

If FDA intends to finalize its proposed Deeming regulation, it must include analysis of the impacts on these countries in its Final Regulatory Impact Analysis, and it should use that information to conclude that premium cigars should not be included in the rule.

Dominican Republic, Honduras and Nicaragua

These three nations form the foundation of the Latin America premium cigar industry. With an estimated 300,000 – 350,000 jobs associated with the agricultural, production and distribution logistics of the industry, these jobs exist in most economically and politically sensitive region. On January 29, 2013, the Ambassadors to the United States from each of these three nations signed a joint letter to the State Department, U.S. Food & Drug Administration, and the National Security Council expressing serious concern as to what the regulation of the premium cigar industry would mean to the region.

The significance of the region was further noted when the Vice President announced a funding initiative for Central America ($1 billion) in which Honduras was specifically noted.

Ecuador

Ecuador has become a principle provider of premium cigar leaf, growing exponentially in popularity, specifically with American consumers. Any threat to production as a result of regulation, can adversely affect the agricultural contribution Ecuador makes to the premium cigar industry.

Mexico

Mexico has become a principle provider of premium cigar leaf, as well as wrapper and filler tobaccos, and has been growing exponentially in popularity, specifically with American consumers. Any threat to production as a result of regulation, can adversely affect the agricultural contribution Mexico makes to the premium cigar industry.

Mexico also has premium cigar manufacturing facilities that would be subject to any proposed regulatory program, making this issue a concern as it pertains to NAFTA implications.

Brazil

Brazil has become a principle provider of premium cigar leaf, growing exponentially in popularity, specifically with American consumers. Any threat to production as a result of regulation, can adversely affect the agricultural contribution Brazil makes to the premium cigar industry.

Indonesia

Indonesia has become a principle provider of premium cigar leaf, specifically for binders and fillers, growing in popularity, specifically with American consumers. Any threat to production as a result of regulation, can adversely affect the agricultural contribution Indonesia makes to the premium cigar industry.

Cameroon

Cameroon is a principle provider of premium cigar leaf, and specifically for prized cigar premium cigar wrapper that is vital to the Latin America – United States premium cigar market. Any threat to production as a result of regulation, can adversely affect the agricultural contribution Cameroon makes to the premium cigar industry.

FDA's Proposed Rule is a De Facto Technical Barrier to Trade

As stated above, approximately 95% of handmade cigars sold in the United States are imported. The user fees that the FDA would impose on premium cigar manufacturers or importers erects a barrier to the importation of the roughly 260 million premium cigars that are currently imported each year, primarily from Latin America. Consequently, the user fee would place a burden on commerce between the United States and the Caribbean Basin countries, thereby violating the spirit of the Dominican Republic-Central America Free Trade Agreement ("DR CAFTA").

A central theme that orbited the signing of DR-CAFTA was that to keep our economy growing and creating jobs, we need to open markets for American products overseas, as well as strengthening the regional economies within the hemisphere. We understood at the time that strengthening our regional economic ties is vital to America's economic and national security interests. Furthermore, we understood that by strengthening economic ties with nations in our hemisphere, we were advancing the stability

that comes from such economic relationships. The purpose of DR-CAFTA was to facilitate trade between the United States and its Latin and Caribbean neighbors, noting that the imposition of a user fee on imported cigars undermines this goal.

Similarly, there are premium cigars imported from Mexico. For the same reason, FDA's proposed rule may represent a de fact technical barrier to trade under NAFTA that would likely be challenged in the WTO.

FDA's Rule Has Adverse National Security Implications

In addition to the economic and legal implications of including premium cigars cited above, there may be very real consequences for American national security. Any regulatory measures that jeopardize employment throughout much of Latin America, by impacting production, could result in adverse internal and external political climate changes. that work against American national interests, and overall economic and political stability in the region.

Again, the handmade cigar industry creates 350,000 direct jobs in the Caribbean Basin. If one considers the families reliant on the premium cigar industry for income, the number of people who would be impacted by FDA regulation of premium cigars explodes to over 1,000,000 individuals (including thousands of jobs employing Haitian farm workers in the Dominican Republic). The industry provides families with living wages, health care and education. By FDA's own account, as many as 50% of existing cigar lines may be forced to exit the marketplace as a direct result of the proposed rule. The negative impact and unintended consequences of this regulation could contribute to the type of economic instability the region has experienced in recent history.

Moreover, President Obama has announced an initiative to advance relations with Cuba. One of Cuba's best-known products – and one sure to be a major export to the United States – is premium cigars. FDA's inclusion of premiums in this rule could result in tension during this critical period and, at a minimum, sends a mixed message in its timing. It also compromises the possibility of American small businesses' benefitting from access to this important market.

The potential economic, legal, and national security implications of FDA's proposed rule are significant and have been left unanalyzed by FDA. If FDA chooses to issue a final Deeming rule, it should fully consider these issues and take that analysis into consideration when determining whether premium cigars should be included.

Market Monopolization by Largest Firms

If FDA includes premium cigars in its final regulation, it is likely to lead to the perverse consequence of driving the vast majority of small-business premium manufacturers out of the marketplace and consolidating the industry in the hands of the largest companies, who are best able to bear the costs of HPHC testing and other regulatory burdens.

Gradual Monopolization of the Tobacco Market

Well-established economic theory demonstrates that raising costs and the burden of regulation in a given sector tends to drive the market toward monopolization. As costs rise, smaller manufacturers are driven from the market. Larger manufacturers are able to take advantage of economies of scale and find it easier to absorb costs. In the tobacco market, this has played out exactly as theory predicts. In the wake of the 1998 Master Settlement Agreement, the cigarette market in the United States has continued to consolidate and is now overwhelmingly dominated by the Big Three manufacturers.[2] Similar trends are almost certain to occur if FDA includes premium cigars in its final rule.

The most likely result of subjecting premium cigars to this FDA regulation is nearly total market consolidation of the premium space into the hands of the largest tobacco companies. Nearly all premium manufacturers are small businesses and will simply not be able to bear the estimated costs of the rule. FDA estimates that as much as 50% reduction in the premium cigars marketplace due to the costs of the rule, and that estimate is based on a cost figure that incorrectly fails to take into account one of the most expensive proposed provisions. Considering that the costs of HPHC testing alone are likely to be nearly $20 million per business in the first year, 50% attrition in the marketplace is an extremely conservative estimate. The reality is that

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2 For more information on tobacco cartelization in the wake of the MSA, see Viscusi, W. Kip, *Smoke-Filled Rooms: A Post-Mortem of the Tobacco Deal*, 2002.

closer to 80% of premium manufacturers are likely to close, and nearly all small manufacturers will be unable to comply.

FDA's $10 Criteria for Premium Cigars is Unworkable and Unnecessary

FDA's proposed Deeming regulation would extend FDA authority to include regulation of cigars, but the rule included two options for coverage: one in which all cigars would be deemed and a second option in which all cigars except "premium cigars" would be deemed. Because FDA does not currently have a regulatory definition for "premium cigars," the Agency proposed to define that term to mean the following:

> A premium cigar is one that "(1) Is wrapped in whole tobacco leaf; (2) contains a 100 percent leaf tobacco binder; (3) contains primarily long filler tobacco; (4) is made by combining manually the wrapper, filler, and binder; (5) has no filter, tip, or non-tobacco mouthpiece and is capped by hand; (6) has a retail price (after any discounts or coupons) of no less than $10 per cigar (adjusted, as necessary, every 2 years, effective July 1st, to account for any increases in the price of tobacco products since the last price adjustment); (7) does not have a characterizing flavor other than tobacco; and (8) weighs more than 6 pounds per 1000 units."[3]

We support this definition of premium cigars with the exception of criterion (6), that each cigar must retail for at least $10. Inclusion of this criterion in the definition will prove impossible to enforce and may result in supply chain disruption, further limitation of variety for consumers, and market exit for many small businesses.

FDA Lacks Authority to Request Pricing Information During Inspection

If FDA's proposed premium definition were to be finalized, it would be difficult or impossible for FDA to enforce because of restrictions in the Food, Drug, and Cosmetic Act. The FD&C Act authorizes FDA inspection of tobacco retail facilities, but clearly states that, "No inspection…shall

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3 Federal Register, Vol. 79, No. 80, Page 23150, Apr. 25, 2014. (Hereafter "Deeming NPRM")

extend to financial data, sales data other than shipment data, pricing data…"[4]

Because the FD&C Act enjoins FDA from collecting any sales pricing data during their inspections of retail stores, it is not clear how the Agency would enforce the pricing criterion. This legal barrier to enforcement is, by itself, sufficient argument that FDA should modify its proposed definition in the final rule by dropping criterion (6).

Ability to Qualify for Exemption from Manufacturing Regulations Would Not Be Under the Control of Manufacturers

FDA's proposed price criterion for the definition of premium cigars will also prove unworkable because it is controlled by retailers, while the majority of regulatory effects are borne by manufacturers.

Cigar manufacturers must know, ex ante, whether their products are covered by the Deeming regulation in order to comply with it. Under the terms of the proposed rule, deemed cigars would be required to, among other things, display new warnings on packaging and receive premarket approval from FDA. In the case of the latter requirement, FDA proposes that the majority of new cigars would need to obtain "substantial equivalence" determinations from the Agency to prove their similarity to products already on the market. Complying with this provision would necessitate extensive and costly testing.

But if FDA's proposed definition of "premium cigars" went into effect, manufacturers would be generally uncertain of their regulatory status and, thus, whether any of these requirements applied to their products or not. Manufacturers who do not sell directly to consumers cannot control the retail price of their products. Attempting to do so could very well run afoul of Federal or state antitrust laws. FDA's definition would create fundamental uncertainty for manufacturers.

Inclusion of Price Criterion is Not Necessary to Achieving FDA's Goals

FDA is concerned that creating an exemption for premium cigars could lead to regulatory arbitrage and that mass-market products might be incentivized to marginally adjust their manufacturing process to gain access to the premium exemption. If enough products were able to do so, this could potentially undermine the public health goals of the proposed rule. FDA states,

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4 21 U.S.C. § 374(a)(1)

> Although the Agency is proposing a definition with respect to Option 2, FDA remains concerned that any attempts to create a subset of premium cigars that are excluded from regulatory authority might sweep other cigar products under its umbrella.[5]

This concern is unwarranted. Excepting the price criterion, there are seven other conditions that a cigar must meet under the proposed definition to qualify as "premium." FDA has carefully constructed their definition to capture only those products meeting this stringent definition. For example, a premium cigar would need to be wrapped in whole tobacco leaf and contain 100% leaf tobacco binder. Leaf wrapper is substantially more expensive, somewhere between 70% and 200% more expensive, than reconstituted homogenized tobacco paper. Further, the homogenized tobacco paper that mass-market brands use is necessary for the machine making process; it is unlikely that a 100% tobacco leaf wrapper could be mass produced by any current process. A switch to long tobacco filler would similarly be substantially more costly for mass-markets.

Doubling the weight of the cigars further delineates premium hand rolled cigars from the mass market products which are a smaller format. Similarly, criterion (4) requires manual construction of the cigar. It is simply not economically feasible to imagine mass-market cigars moving from machine construction to manual construction, because doing so would dramatically increase the price of the product for consumers. These other elements of the definition can therefore be thought of as a self-executing price qualifier, necessarily dictating significantly higher price points than other tobacco products.

In addition to the criteria that would make mass-produced premium cigars unfeasible, FDA's proposed definition would also require that premium cigars lack tips, filters, or characterizing flavors. All of these are important qualities of mass-market cigars: Public policy health advocates have noted that these characteristics have been associated with youth usage issues. All of these practices would be impermissible under FDA's proposed criteria.

The quality criteria are not easy to avoid and companies cannot simply commit arbitrage by making minor changes to their manufacturing processes. FDA has wisely learned from previous experience in this area. We believe that the other seven proposed criteria are sufficient to limit exempted products to those that are truly premium cigars. Mass-market products that FDA intends to capture

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5 Deeming NPRM

under the Deeming rule are very unlikely to be able to qualify for exemption even in the absence of any price criterion.

Tightening the Weight Criterion As a Further Guarantee Against Arbitrage

While the price criterion is not necessary to ensure that regulatory arbitrage does not occur, we believe that, if FDA wishes to further ensure the integrity of the "premium" definition, it should re-examine and further tighten criterion (8), which limits the category to a weight of more than 6 pounds per thousand units. The weight criterion is fundamentally designed to ensure that cigarette lookalikes cannot take advantage of a potential premium exemption. We believe that FDA should consider revision the weight criterion upward to more than 8 pounds per thousand units. This change would provide the Agency with additional protection from regulatory arbitrage and would prevent large tobacco manufacturers from taking advantage of an exemption not designed for their products.

FDA Failed to Estimate One of the Rule's Most Significant Costs

HPHC Testing

Executive Order 12866 requires FDA to assess all costs and benefits of its rulemaking, to the extent that it is feasible to do so, prior to issuance of a final rule.[6] The goal of E.O. 12866 is twofold. First, disclosure of costs and benefits provides transparency to the public, including the affected industry and other interested parties. Second, an assessment of costs and benefits is intended to inform the regulatory process and to help FDA adopt policies that "impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and government entities), consistent with obtaining the regulatory objectives." FDA's proposed Deeming rule failed to assess some of the most critical costs and benefits to the regulated industry. The proposed rule thus lacks that transparency and accountability required by E.O. 12866.

6 E.O. 12866, available at: http://www.archives.gov/federal-register/executive-orders/pdf/12866.pdf

If finalized, FDA's proposed rule would require all deemed products entering commerce after February 15, 2007 to receive premarket approval. All products introduced after this "grandfather date" would either need to demonstrate their "substantial equivalence" to an existing product or submit a detailed application demonstrating that their marketing is appropriate for the protection of public health. The latter pathway is expected to involve much more detailed and burdensome submissions, and FDA's proposed rule makes clear that the Agency expects nearly all cigar manufacturers will pursue a determination of substantial equivalence for their products. Obtaining a determination of substantial equivalence requires manufacturers to submit descriptions of their products (and the comparison predicates), as well as scientific information on their "harmful and potentially harmful constituents."

The HPHC reporting required of each post-grandfather product will be a major cost-driver of the rule and will be particularly burdensome on manufacturers of premium cigars. Premium cigar makers generally do not have in-house laboratories and will thus need to contract with independent labs to perform that testing. FDA chose not to estimate any of these costs in the preliminary RIA:

> Although this provision would create an obligation that imposes costs, the Secretary is also required to promulgate regulations concerning the testing and reporting of constituents. We will estimate the cost of compliance with testing and reporting when those regulations are promulgated…[7]

This failure to include the costs is unjustified, as FDA has already published guidance outlining its policy on HPHCs. In 2012, the Agency issued a document outlining 93 constituents that it believes are harmful or potential harmful in tobacco products. Because of the extensive nature of that list, FDA further explained that it is currently requiring testing only on a subset of 20 of those HPHCs. Thus, the policy regarding HPHCs is already well established for items already under FDA's authority. While FDA is expected to determine new HPHCs for newly deemed products, there is no reason to believe that the list will be substantially different for cigars as opposed to cigarettes. Certainly the established HPHC list at least provides sufficient precedent for FDA to use as a baseline economic estimate. Including these calculations as a baseline estimate is much more transparent and within the spirit and letter of E.O. 12866 than simply providing no estimate of a major cost-driver at all. Even if FDA did intend to adopt a

7 Deeming Rule Preliminary Regulatory Analysis (RIA), 79 FR 23141 (April 24, 2014) at 33.

narrower HPHC list for cigars, that subsequent rulemaking could revise the economic information; but there is no good reason that the costs of this testing should not be accounted for in the rulemaking at hand. In fact, doing so is clearly required by E.O. 12866.

A Preliminary Estimate

Estimating the costs of HPHC testing is vital to understanding the impact of FDA's proposed rule, and any final rule must take them into consideration in its cost-benefit calculation. In an attempt to help FDA make these estimates, CRA contacted two independent labs to attempt to determine what a straightforward HPHC test for a substantial equivalence would likely cost. Both labs returned similar figures: testing of each product is likely to fall, at minimum, around $20,000. It's important to emphasize that this is not an inflated figure designed to place an upper bound on the likely cost.

That figure refers to testing only the abbreviated list of HPHCs, not the full list of 93 constituents.[8] (The labs we spoke with estimate the costs of testing the full list at approximately $60,000 per product.) Although FDA has made no such commitment, we assume for the purposes of our analysis that the final rule will require testing only for the abbreviated list.

The labs we spoke with also emphasized that their estimates were based on their experience with cigarettes and that, because premium cigars are likely to be harder to analyze, the $20,000 figure should be viewed as a floor rather than a ceiling. They cited several fundamental challenges to analyzing cigar HPHCs that they believe are likely to result in substantial increases in cost for manufacturers. First, there is no recognized testing methodology for analyzing cigar smoke, as there is with cigarettes. Labs will need to develop and standardize entirely new testing methodologies, in the absence of which all collected data would be useless. This development process is likely to take a substantial amount of time and to significantly add to the time and cost of the initial round of cigar testing. These monetary and time costs are not estimated here. Second, while cigarettes come in standardized diameters, allowing them to be easily analyzed, this is not the case for cigars, and for premium cigars in particular. Premiums vary substantially in size and diameter. In addition to the methodological challenges that this variation poses, labs will also be required to purchase new equipment to accommodate the different products. We have not attempted to estimate any of these capital

8 The full list of HPHCs is available at http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm297786.htm

costs in this analysis. Thus, $20,000 is an extremely conservative estimate of the cost of HPHC testing for an SE application.

To estimate the total impact, that cost figure, should be multiplied by the total number of products likely to be affected. FDA estimated that 3,639 different premium cigars would likely be affected by the rule.[9] CRA believes that number is low. We commissioned a survey of all of our members, as well as other manufacturers in the premium cigar space. We received responses from a total of 17 companies including the entire range, from small firms manufacturing only a handful of products, to medium-sized firms, to large firms. Taken together, our survey covers approximately 80% - 90% of the premium cigar market.

We asked both how many SKUs respondents manufacture each year and then asked them to report on the number of cigar types likely to be affected by the application requirements (i.e. how many types with substantial differences likely requiring an SE report). Our respondents collectively manufacture 4,628 products that will likely be required to obtain SE approval from FDA (an average of 272 products per manufacturer). Extrapolated across the industry as a whole, that implies a total number of likely-affected, premium products of 5,444.[10] At a minimum of $20,000 per application, the HPHC testing alone will cost premium manufacturers a collective $108.9 million in preliminary testing, or an average of $5.44 million per business. (Testing for the full list of HPHCs would cost $326.6 million in total, or $19.2 million per business.)

FDA also attempted to estimate costs in recurring years, based on the introduction of new products to the marketplace, each of which would require an SE application. The RIA assumes that somewhere between 5% and 15% of each year's product line is new,[11] but our survey of manufacturers found that even their upper bound was well below the correct figure. In fact, our figures show that between 18% and 32% of premium products are new each year, indicating a significantly higher degree of innovation and response to market demand than FDA anticipated.[12] Again, we attempt to make a conservative estimate of these ongoing costs by using the lower bound

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9 RIA at 26

10 Assuming that our survey covered 85% of the premium market. Given the breadth of FDA's interpretation of the type and scope of change that renders a product a new tobacco product, that estimate is likely to be low.

11 RIA at 28.

12 The lower bound represents introduction of "unique products" and the upper bound represents new SKUs. The lower bound is used for subsequent calculations.

of 18% from our manufacturer survey. In order to complete only the HPHC portion of these continuing SE applications, costs of $19.66 million ($0.98 million per business) would accrue to manufacturers in each ongoing year.[13] (Testing for the full list of HPHCs would cost $58.8 million per year in total, or $3.5 million per year per business.)

As is evident from this information, the costs of HPHC are highly significant and, in fact, the primary costs of this rulemaking. FDA's failure to estimate them violates the letter and spirit of E.O. 12866. It fails to provide transparency to the public and falls below the standards for evidence-based policymaking. FDA must include these costs, should it opt to finalize any Deeming rule.

Conclusion

Executive Orders 12866 and 13563 require FDA to analyze the costs and benefits of their regulation and to demonstrate that the costs are justified by the benefits. As you know, the critical importance of these principles is not only enshrined in OIRA's EOs, but was recently reified by the Supreme Court.[14] In the case of premium cigars, FDA has failed to meet its obligation to adequately analyze the impacts of its action, and we believe, cannot possibly justify it, given the evidence.

FDA cites as its primary reason for regulating premium cigars an "epidemic" of youth usage. There is no such epidemic. March 2015 CDC data demonstrates that, at most, 0.08% of high-school age youth report access to even one premium cigar, and that figure has been in ongoing decline for a number of years. While youth access to mass-market cigars is, indeed, cause of concern, there simply is no evidence to demonstrate that the regulation would significantly reduce youth access to premium cigars – there already is nearly no significant access.

While FDA has not made the case for the benefit of Deeming premiums, they have dramatically underestimated the costs of doing so. On the Agency's own estimate, as much as 50% of the premium market would be eliminated by the rule. While that would be devastating for the industry, it should be considered a lower bound, because FDA has failed to even attempt to estimate the rule's primary cost-driver. FDA would require essentially all new cigar products to submit HPHC testing data, which we demonstrate would conservatively cost $20,000 per product. Given the frequency with which new blends and varieties are introduced, these costs are simply not tenable for the

13 0.18(5,444 total products) * $20,000 = $19.6 million; 0.18(272 products on average) * $20,000 = $0.98 million.

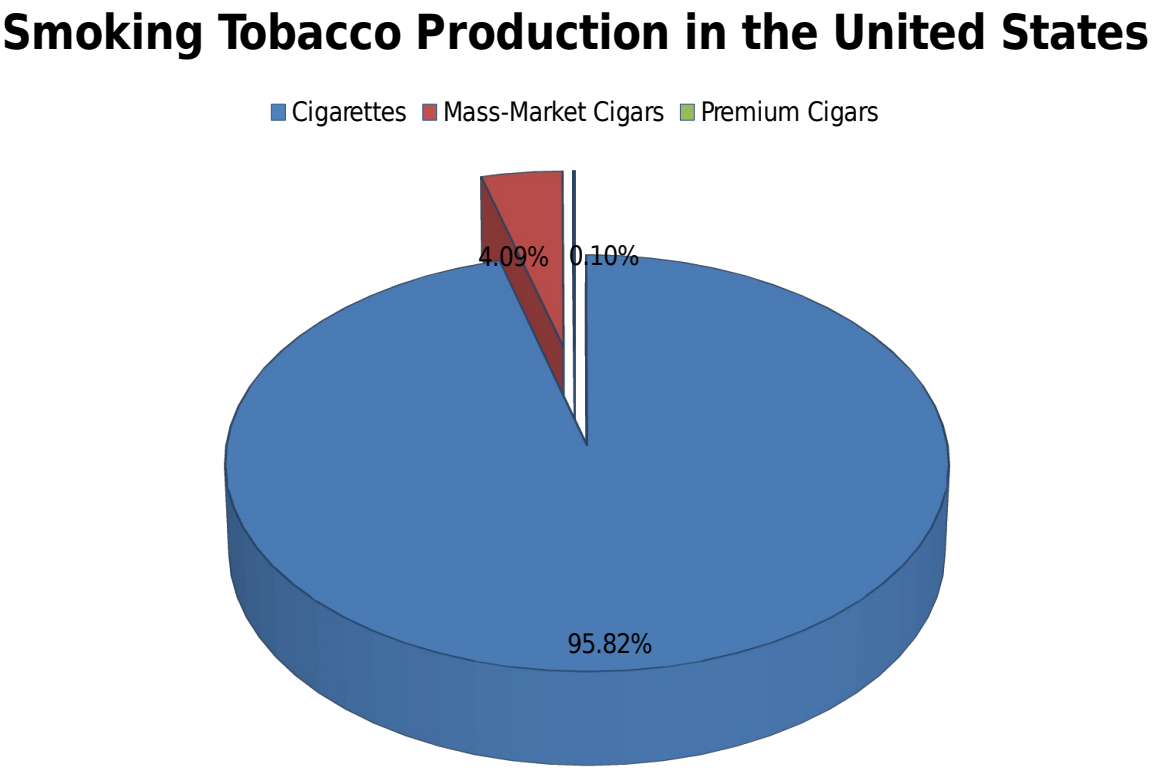
14 *Michigan et al. v Environmental Protection Agency et al*, June 2015.

industry, particularly as it is composed of small businesses. The unintended consequences of FDA's proposal are unavoidable: it will result in tens of thousands of lost jobs in the United States and potentially hundreds of thousands of jobs in Latin America. As small businesses, very few premium cigar manufacturers could even hope to accommodate the costs suggested by FDA's proposal and most would be driven out of the marketplace. Ironically, the effect would almost certainly be to consolidated what little remained of the premium industry in the hands of the legacy Big Tobacco companies, companies that helped to draft the TCA and that can use their economies of scale to absorb the various costs of the rule.

While it might be beneficial for FDA to regulate many cigar products, it cannot possibly be justified for premium cigars, a category for which there are nearly no demonstrated benefits and extremely high costs. FDA recognized this in the proposed rule by including Option 2, an exemption for the premium category, but had concerns that any definition might be over-inclusive and allow for regulatory arbitrage. Those fears should be allayed: with a minor change, FDA's definition for premiums can successfully exempt the products that need to be exempted while preventing free riders. FDA's definition focuses on intrinsically costly measures of cigar quality. By their very nature, it is not possible for mass-market cigars to mimic these qualities. Out of an abundance of caution, we would support a further tightening of FDA's eight criterion for premiums, raising the weight threshold from 6 to 8 pounds per thousand units. This is more than sufficient to effectively exclude mass-market products.

FDA's proposed deeming of premium cigars has few or no benefits, huge costs, and serious unintended consequences. The Agency should select, and OIRA should recommend, the Option 2 exclusion for premium products.

Appendix:
Premium Cigars Represent a Tiny Proportion of the Total Cigar Market and a Vanishingly Small Proportion of Total Smoking



Cigar Production in the United States